



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10518]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[Insert date 60 days after the date of filing for public inspection at the OFR]**:

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-10518 Application for Participation in the Intravenous Immune Globulin (IVIG)

Demonstration

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Application for Participation in the Intravenous Immune Globulin (IVIG) Demonstration; Use: Traditional fee-for-service (FFS) Medicare covers some or all components of home infusion services depending on the circumstances. By special statutory provision, Medicare Part B covers intravenous immune globulin (IVIG) for persons with primary immune deficiency disease (PIDD) who wish to receive the drug at home. However, Medicare does not separately pay for any services or supplies to administer it if the person is not homebound and otherwise receiving services under a Medicare Home Health

episode of care. As a result, many beneficiaries have chosen to receive the drug at their doctor's office or in an outpatient hospital setting. On Tuesday, January 3, 2012, the President signed into law the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012". The act authorizes a 3-year demonstration under Part B of Title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the in-home administration of IVIG for the treatment of PIDD.

The statute limited the demonstration to 4,000 beneficiaries and \$45 million, including administrative expenses for implementation and evaluation as well as benefit costs. The statute also required that an evaluation of the demonstration be conducted. Under this demonstration, Medicare will issue under Part B a bundled payment for all medically necessary supplies and services to administer IVIG in the home to enrolled beneficiaries who are not otherwise homebound and receiving home health care benefits. In order to implement the demonstration and ensure that statutory limits are not exceeded, it is necessary to positively enroll beneficiaries in the demonstration.

This collection of information is for the application to participate in the demonstration. Participation is voluntary and may be terminated by the beneficiary at any time. Beneficiaries who do not participate will continue to be eligible to receive all of the regular Medicare Part B benefits that they are would be eligible for in the absence of the demonstration. Form Number: CMS-10518 (OCN: 0938-NEW); Frequency: Annually; Affected Public: Individuals and households; Number of Respondents: 4,000; Total Annual Responses: 4,000 Total Annual Hours: 1,000. (For policy questions regarding this collection contact Jody Blatt at 410-786-6921.)

Dated: March 4, 2014

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Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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